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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,857	05/11/2005	Ross E. Mantle	10517-700-US0	7154

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EXAMINER	
WIEST, PHILIP R	
ART UNIT	**PAPER NUMBER**
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,857	MANTLE, ROSS E.	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/270/7*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 18-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 18-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 May 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

In the response filed 9/27/07, applicant added new claims 18-37. Claims 1-13 and 18-37 are currently pending.

Drawings

The drawings were received on 9/25/07. These drawings are accepted.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-9, 11-13, 18, 19, 21-23, 27-30, 32-34, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (US 4,450,841) in view of Leonard (US 3,927,980), and further in view of Ginsburg et al. (US 6,497,721).

3. Osterholm discloses an apparatus for modulating the temperature and pressure within a body cavity by means of recirculating of a biologically compatible liquid, the apparatus comprising a first pump means 18 for infusing liquid at a controlled temperature and flow rate into the cavity, means for monitoring temperature of fluid (14, 40), and means for monitoring pressure of the fluid (18, 38). Osterholm, however, does not disclose that the monitoring means monitor temperature and pressure within the cavity, nor does it teach a second pumping means for withdrawing liquid at a controlled rate from the cavity.

4. Regarding Osterholm's lack of a second pumping means, Leonard discloses an extracorporeal system comprising a first pump 36 capable of infusing a liquid and a second pump 40 capable of withdrawing a liquid at a controlled flow rate (see Figure 1). The use of a plurality of pumps and a liquid storage means allows fluid to be withdrawn from the cavity at a different than it is infused, such that the pressure within the cavity can be controlled. When controlling the pressure within a cavity, is it obvious that pressure changes may be realized by changing the amount of fluid present within the cavity. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm with the plurality of pumps of Leonard so that the flow rate of fluid into and out of the cavity may be controlled, thereby regulating the pressure within the cavity.

5. Regarding Osterholm's lack of monitors within the cavity, Ginsburg et al. (hereafter "Ginsburg") discloses an apparatus for regional temperature modification wherein cranial pressure and temperature may be monitored and controlled (Column 5, Lines 58-65, Column 14, Lines 49-59, and Abstract). While Osterholm does disclose the monitoring of temperature and pressure, it is done so within the liquid storage chamber and not within the body. It is obvious that temperature measurements will be more accurate inside the body than in a fluid reservoir. Additionally, taking internal pressure measurements allows the pressure within the cavity to be controlled. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm with the use of internal pressure and temperature monitoring of Ginsburg in order to more accurately monitor the pressure and temperature inside the cavity, thereby allowing the apparatus to change the flow rate and heat transfer settings accordingly.

6. With respect to Claim 6, Osterholm discloses a liquid storage means (10, 12, 14, 16, and 28) situated between the inflow and outflow catheters. The liquid storage means draws fluid from the outflow catheter, treats the fluid, and pumps the fluid back into the body cavity (see Figure 1).

7. With respect to Claim 7, Osterholm discloses a first catheter (connecting the spinal subarachnoid space 26 and the output collection 28) and a second catheter 30 to withdraw liquid from the cavity to the liquid storage means.

8. With respect to Claims 8 and 9, Osterholm discloses means to oxygenate and adjust the pH of the liquid (Column 14, Line 55 through Column 15, Line 21).

9. With respect to Claim 2, Osterholm in view of Leonard and Ginsburg discloses the apparatus of Claim 1, wherein fluid is circulated out of and back into the body through lumens connected to pumps (see the above rejection). Ginsburg further discloses the use of a dual-lumen catheter comprising an inflow lumen and an outflow lumen to circulate fluid into and out of a body region (see Figure 2). The use of dual-lumen catheters to circulate a liquid or introduce multiple fluids is established in the art because they allow a single incision to be made in the skin, thereby reducing the pain that a patient experiences. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm in view of Leonard and Ginsburg with Ginsburg's use of a dual lumen catheter because doing so would enable fluid to be circulated in and out of a body while reducing the number of incisions necessary from two to one.

10. With respect to Claims 3-5, Osterholm discloses a further catheter 30 connecting the cavity and the liquid storage means. The further catheter withdraws fluid from a different part of the brain such that treatment may be focused at specific areas of the cavity (Column 13, Lines 4-29). Osterholm, however, does not specifically disclose the use of a pump to withdraw fluid from the cavity through the further catheter. As explained above, Osterholm in view of Leonard and Ginsburg disclose an apparatus for circulating fluids in a body cavity comprising a pump to move fluid through the catheter

and pressure and temperature monitoring means that control the pump. This configuration allows fluid to be drawn from the catheter at an optimal rate as determined by the sensors. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the further catheter of Osterholm with the catheter pumping and monitoring means of Osterholm in view of Leonard and Ginsburg in order to provide controlled flow from a second position within a body cavity such that treatment may be localized at specific points within the cavity.

11. With respect to Claims 11 and 12, Osterholm in view of Leonard and Ginsburg discloses the device of Claims 1 and 6, and that temperature and pressure sensors may be placed at the tip of a catheter such that they record the temperature and pressure inside a body cavity (see rejection above). The pumps may controlled in order to control the pressure inside the cavity (see Osterholm: Column 14, Lines 28-33). Furthermore, Ginsburg discloses a pump that is responsive to the difference between the temperature in the cavity (reference temperature) and the temperature in the liquid storage means (Column 22, Lines 36-47). Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the device of Osterholm in view of Leonard and Ginsburg with the temperature-based pump control of Ginsburg and the pressure-based pump control of Osterholm because doing so would allow both temperature and pressure to be controlled by altering the flow rate of fluid into and out of the cavity.

12. With respect to Claim 13, Osterholm discloses means 18 responsive to the pressure sensed pressure monitoring means 38. Osterholm, however, does not disclose that said pressure monitoring means are disposed within the cavity. As explained above, Ginsburg discloses a device wherein temperature and cranial pressure are monitored in order to control the system (Column 14, Lines 49-59). These internal pressure measurements allow the pressure in the system (i.e. speed of the pump) to be controlled such that pressure in the cavity reaches an optimal level. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm in view of Leonard and Ginsburg with the use of internal pressure and temperature monitoring of Ginsburg in order to more accurately monitor the pressure and temperature inside the cavity, thereby allowing the apparatus to change the flow rate and heat transfer settings accordingly.

13. With respect to Claim 20, Osterholm, Leonard, and Ginsburg disclose the device substantially as claimed (see rejection above), wherein a sensor is placed inside the body in order to monitor temperature. Ginsburg further discloses that the temperature sensor is attached to the tip of the catheter to sense the temperature of fluids in the body (see entire disclosure). Based on the sensed temperature, the system heats or cools the withdrawn fluid to achieve a desired body temperature. The placement of temperature sensors at the distal end of a catheter is well established in the art because it allows the temperature of body fluids at the fluid withdraw point to be easily monitored. Therefore, it would have been obvious to one of ordinary skill in the art at the time of

invention to try modifying the catheter system of Osterholm, Leonard, and Ginsburg with the temperature sensor at the distal tip of the catheter of Ginsburg in order to provide a simple, alternate means for measuring temperature inside the body. Providing the sensor integrally with the catheter would prevent the need to separately insert a sensor into a body cavity.

14. With respect to Claims 25 and 26, Osterholm, Leonard, and Ginsburg disclose the device substantially as claimed. Leonard further discloses that the device comprises a first recepticle 14 for storing liquid to be introduced into the patient's body, and a second receptacle 12 for collecting liquid removed from the patient's body. The first and second recepticles are coupled by a recirculation line 42. The recirculation line balances the system and protects from over-pressure due to fluid accumulation, therefore ensuring that fluid is able to be constantly infused into the body at the desired rate. For this reason, the use of reservoirs and recirculation lines are extremely common in the art of physiological fluid treatment devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Osterholm, Leonard, and Ginsburg with the inlet recepticle, outlet recepticle, and connecting recirculation line of Leonard in order to provide proper fluid and pressure balancing for the system, thereby optimizing the rate of fluid flow to the patient.

15. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm in view of Leonard, and further in view of Ginsburg and Guitierrez-Collazo (US 5,562,821). Osterholm in view of Leonard and Ginsburg disclose the device of Claims 1 and 6 (see rejection above). Osterholm further discloses that the liquid is sterilized by sterilization unit 32 and harmful chemicals are removed by filter element 12 (see Figure 1) while in the liquid storage means, but does not specifically disclose contaminants are removed by foam fractionation. Guitierrez-Collazo discloses a foam fractionation device that removes contaminents from an aquatic environment by creating a vortex. This method of purification is well established in the art of fluid filtration as a method of removing organic compounds in order to prevent the build-up of bacterial byproducts, which could cause infection (Column 2, Lines 21-30). Therefore, it would have been obvious to one skilled in the art at the time of invention to combine th device of Osterholm in view of Leonard and Ginsburg with the use of a foam fractionator of Guitierrez-Collazo in order to provide an alternate means for removing contaminants from the liquid before returning it to the body.

16. Claims 24, 31, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Osterholm in view of Leonard and Ginsburg, and further in view of Maginot (US 6,743,218). Osterholm, Leonard, and Ginsburg disclose the device substantially as claimed (see rejection above), but do not disclose that the inlet and outlet catheters are arranged as a single dual lumen catheter. Maginot discloses a dual lumen catheter that is used to move fluids in and out of a fluid cavity. The use of dual

lumen catheters is extremely common in a wide variety of physiological fluid treatment methods because they allow fluids to be removed from and returned to the body through a single catheter, thereby requiring only a single incision to be made. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the treatment device of Osterholm in view of Leonard and Ginsburg with the dual lumen design of Maginot in order to reduce the number of incisions required, thereby improving patient comfort and reducing the risk of surgical complications.

Response to Arguments

17. Applicant's arguments filed 9/25/07 have been fully considered but they are not persuasive. Applicant argues that Osterburg in view of Ginsburg does not suggest the placement of a temperature sensor within a body cavity, and that there is no motivation to combine the Osterholm and Ginsburg references.

18. Regarding applicant's argument that Ginsburg does not disclose the monitoring of temperature within the body cavity, the sensors may be disposed at the tip of the catheter, as shown in the figures, or inserted into the body separately. Therefore, these sensors would obviously be disposed in the cavity when the treatment is being performed. Furthermore, Ginsburg anticipates the use of external sensors 348 and 349 to monitor the temperature of the selected body regions, such as the brain region. Therefore, Ginsburg discloses that pressure in the brain cavity may be monitored by a multitude of different sensors.

19. Furthermore, the fact that Ginsburg discloses the use of the catheter in a blood vessel is irrelevant. Osterburg clearly anticipates the need to regulate the temperature of fluid being infused into a body cavity, and places a temperature monitor in the outlet catheter. The only thing from the Ginsburg reference is used for it to show various placements of temperature and pressure sensors within the body.

20. Regarding new claims 18, 28, and 32, Osterholm does, in fact, disclose the step of pumping fluid into and out of the cavity. Osterhom discloses a pressure and flow rate monitor and adjustment means (18, 38) (i.e. peristaltic pump) that controls the flow of fluid through the system. Additinally, Osterholm discloses a monitoring system (34, 36, 38, 40, 42) that functions to maintain a plurality of condition values.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
1/3/08

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